Remarks

I. This acknowledges with appreciation the courtesy of Examiner Carrie Dorna and Supervising Examiner Charles Marmor in granting the Interview on August 2, 2010 with the inventor herein, Professor Giulio Nicita and the undersigned counsel for applicant. Professor Nicita is an internationally known and respected expert as a surgeon, professor and researcher in the fields of urology, gynecology and surgery, and holds the title of Chairman of the Urology Department of the University of Florence Italy Medical School, and President of the Urogynecology Association of Italy. In that capacity he presented an anatomical and surgical explanation and discussion of the present invention and of the cited prior art.

During said interview certain proposed new device and method claims were presented to replace the independent claims rejected in the outstanding Office Action dated July 19, 2010. Also, during said interview applicant's arguments traversing the 35 U.S.C. §103 rejections in said Office Action were presented orally and with PowerPoint illustrations. These arguments will be re-presented below.

II. Status of Claims

In the present response all the rejected Claims 31-35, 55, 60 and 62-66 are canceled without prejudice and replaced by new Claims 68-83. The previously allowed Claim 67 remains with slight amendments for better accuracy.

III. The Rejections Under 35 U.S.C. § 112, Second Paragraph

These rejections on pages 2-5 of the Office Action are believed to be moot and/or overcome by the new claims. In particular, all objections on indefiniteness and improper antecedents are believed to be overcome, essential steps are included in the method claim, and in Markush claims indefiniteness is avoided. Specific issues of indefiniteness will be addressed in later discussion of individual claims.

The currently pending claims are device Claims 68-78 and method Claims 79-82. Claims 68, 74, 76, 78 and 79–82 or their equivalents were discussed during said interview. The distinctions between the claims are as follows. In the Claims and Remarks the terms front and anterior are used as synonyms and rear and posterior are used as synonyms.

1. Device Claim 76 includes a trapezoidal shaped central body with a hole and with front arms extending symmetrically and generally coaxially outward, and with a cleft extending from said hole to one of said front and rear edges or to one of said opposite side edges.

2. Device Claim 77 depends on Claim 76 and defines more specific dimensions of the device.

3. Device Claim 78 is similar to Claim 76 with front arms extending generally coaxially, but the central body is not limited to a trapezoidal shape.

4. Claim 68 defines a device with a central body having a width the maximum dimension of which is designated W. The front arms extend symmetrically outward and have distal ends spaced apart from each other a distance greater than W, and the distal ends of the rear arms are similarly spaced apart from each other a distance greater than W, and the cleft extends from the hole to the terminal edge of the rear portion of the central body.

5. Device Claim 69 defines said front arms as extending generally coaxially outward.

6. Device Claim 70 defines said front arms as extending generally perpendicularly to the central longitudinal axis of the central body.

7. Device Claims 71-73 define with further structural limitations.

8. Device Claim 74 is similar to Claim 68, but the cleft extends selectively to one of said front and rear terminal edges or to one of said terminal side edges of said central body.

9. Claim 79-82 define different method embodiments of this invention.

IV. Rejection of Claims 31-66 Under 35 U.S.C. § 103(a): (i) as obvious over Landgrebe et al. in view of Rehil, or (i.e.) as obvious over Landgrebe et al. in view of Rehil and one or more additional prior art references.

These rejections as they apply to rejected Claims 31-66 and to new Claims 68-83, are respectfully traversed, as discussed below.

Landgrebe et al. is cited for disclosing all the elements (or steps) of the present device claims and method claims respectively, except for the hole and cleft, and Rehil is cited for disclosure of an implantable device having a hole and cleft; the rejection proposes to combine these features.

It is respectfully submitted that the remarks herein will demonstrate:

(a) that the Landgrebe et al. discloses a significantly different structure and fails to disclose numerous material and critical features of the present invention,

(b) that the Landgrebe et al. procedure is so different and contradictory to that of the present invention, that it is not an appropriate or obvious prior art reference for consideration,

(c) that the Langrebe et al. device would require massive reconstruction if one were to even attempt to use it in the present invention,

(d) that the Rehil device is for a purpose unrelated and contrary to that of the present invention and not appropriate or obvious for combination with Landgrebe et al.

(e) that Landgrebe et al. and Rehil, when correctly understood, and even if combined as proposed in the rejections, will not and cannot provide the claimed device and method,

(f) that it would not be obvious to modify Langrebe et al. to combine it with Rehil, to result in the present invention, and there is no teaching, motivation or suggestion to do so, and

(g) that Langrebe et al. and Rehil are so different in their fundamental objects that they teach away from the present invention.

V. Discussion of the Cited Prior Art

Before formally addressing the issues raised in the Office action, it is requested that the Examiner review the appended Exhibit A which is a print-out of the Power Point presentation previously provided by the inventor during the above-referenced interview or the Examiner view the digital version of this presentation which is attached hereto.

The Power Point Page Titles and subject matter are as follows. The term "Nicita" when used is intended to mean the invention of the subject application.

Page 1 – Title

Page 2 – Illustrations of normal anatomy, anterior prolapse and total prolapse

Page 3 – Illustrations of pelvic floor muscles

Page 4 – A preferred embodiment of the present device (of Nicita).

Page 5 - Structure of Landgrebe et al. device.

Page 6 - Structural differences: Nicita vs. Landgrebe et al.

Page 7 - Functional differences: Nicita vs. Landgrebe et al.

Page 8 - Purpose differences: Nicita vs. Landgrebe et al.

Page 9 – The surgical approach is different

Page 10 – The four anchoring points are different

Page 11, 12 – The final position in the pelvis is different

Page 13, 14 – Normal female pelvic floor

Page 15 – The final position in the pelvis is different

Page 16 – The instant device function

Page 17 – Landgrebe device function

Page 18 – Demonstration of possible attempt to convert Landgrebe to the present invention

Page 19 – Conclusion

In these Remarks all references to the present invention as having a trapezoidal shape are intended to refer to the preferred embodiment disclosed in the present application; however, the present invention and various claims herein are intended to not be limited in shape to a trapezoid.

VI. Further Discussion of Langrebe et al.

1. The Langrebe et al. device is for abdominal surgery (an incision in the abdomen) which is totally different from vaginal surgery (implantation up through the vagina) of the present invention.

The illustration below shows how the upper or anterior arms 5 and 6 in Fig. 1 of Langrebe et al. become secured to ligamentum pubicurm superior, and the lower or posterior arms 7 and 8 are extended upward and secured to the muscle rectum abdomis, this device supporting only the bladder. This surgery could not be done by vaginal insertion of the present invention.

Fig. 1 below shows the placement of the Landgrebe et al. device in the female pelvis area; this corresponds to pages 6 and 16 in the Appendix.

Positioning of Landgrebe's device

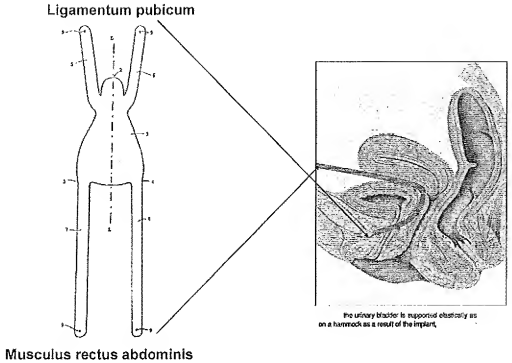


FIGURE 1

It is evident that this device of Landgrebe et al. can support only the bladder, for surgical treatment of urinary incontinence, (see col. 1 lines 40-42, 53-54); this device cannot support other female pelvic organs, and at best, this device is for use when the pelvic floor is still functional and the uterus is still in its correct anatomical position.

The rejection states that Landgrebe's device is "for supporting female pelvic organs"; however, Landgrebe et al. has a far more limited objective, namely, suspension of the urinary bladder (Column 1, lines 3-5), and "to provide an implant for reliable treatment of urine incontinence in women" (Column 1, lines 33-35).

The device of Landgrebe et al. has a triangle-like or elongated oval shape and the bridle-like projections (5,6 and 7,8) which are suitably designed for supporting "elastically as on an hammock the urinary bladder" (see col. 1, lines 53-54) and for being anchored by two projections at ligamentum pubicum and the other two projections at the muscle rectum abdominis.

Projections 7 and 8 are essentially opposite in direction (downwards) with respect to projections 5 and 6 (upwards, see Landgrebe et al., Fig. 1 and col. 2, lines 48-51). Projections 7 and 8 are essentially parallel each other (see Figure 1 and col. 2 lines 51-54) and are longer than projections 5 and 6 (see claim 4).

Projections 5 and 6 are essentially parallel with respect to the longitudinal axis L-L of the device and start at a certain distance from the corner 2 (see col. 2 lines 36-44). It is therefore evident that the two projections 5 and 6 are essentially parallel to each other and are directed upwards (or at most each slightly diverging of a 20° angle from the longitudinal axis L-L, see col. 2, lines 38-44), but for certain they cannot be considered as coaxial or oppositely directed.

In geometry coaxial means that two or more lines or forms share a common axis. The rejection states that these two arms of Landgrebe are coaxial when the device is folded in half longitudinally. It is respectfully submitted that this assertion is incorrect, and that such is a proposed alteration or conversion would result in a non-usable device for Landgrebe or for applicant. If the device were folded in half longitudinally, firstly it is no use for supporting the bladder. As seen the two arms are arranged symmetrically about the longitudinal axis L-L (see col. 2, lines 41-44). If the device were folded pursuant to the rejection, these arms would overlie each other becoming parallel and projecting in the same direction, and thus cannot be coaxial or oppositely directed. A still further difference in Landgrebe's device is the presence of a semicircular or oval extension positioned between projections 5 and 6; this is needed for supporting the bladder neck (see claim 5, col. 6 lines 1-7) and would have to be removed.

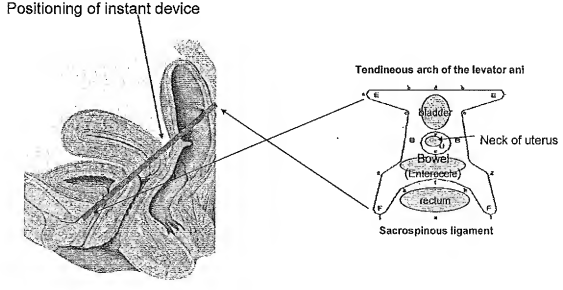
Furthermore, it should be noted that Landgrebe's device is unidirectionally extendable in length (longitudinally, see col. 3, lines 50-51). This is required to allow filling and empting of the bladder. Therefore Landgrebe is silent about:

- shapes of the central portion of the device (base 1) other than triangle-like or oval elongated;

- disposition of the projections (5 and 6, 7 and 8) at angle higher than 20° with respect to axis L-L;
- disposition of projections 5 and 6 in a manner that they do not go in opposite directions with respect to projections 7 and 8;
- anchoring points of the projections other than to ligamentum pubicum and muscle rectum abdominis;
- use of a central hole in the central portion of the device, because such would have been detrimental or of benefit in the Landgrebe device.

VII. Positioning of the Presently Claimed Device in the Female Pelvis

The present invention is further described and illustrated in Fig. 2 below, particularly positioning of this device in the female pelvis, see also page 16 in the Appendix.



FIGUER 2

The two front arms of the present device (i.e. arms E) branch off the smaller base of the (isosceles) trapezoid body of the device. These arms are coaxial and

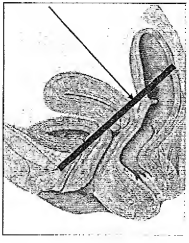
parallel to the smaller trapezoid base and extend in opposite directions. These arms become fixed at the tendineous arch of the levator ani (one at right side and the other at left side). The two rear arms of the device (i.e. arms F) branch off the larger base of the trapezoid body. These arms are divergent from each other and generally parallel to the slanting sides of the trapezium, and become fixed at the sacrospinous ligament.

The positioning of the present invention is completely different from that of Landgrebe device. By positioning as above shown, the new device has been designed, with the included hole of suitable dimension for surrounding the uterus. Said hole is positioned in the central portion of the trapezoid body and a cleft extends from this hole to one of the posterior, anterior or side edges of the device. With the cleft the device can be manipulated until the device is correctly positioned in the pelvis with the hole surrounding the uterus.

PRESENT INVENTION vs. LANGREBE

Figure 3 below demonstrates structural and functional differences between the present invention and the device of Landgrebe and their completely different positioning in the female pelvis, see also page 16 in the Appendix.

Instant device



Landgrebe's device

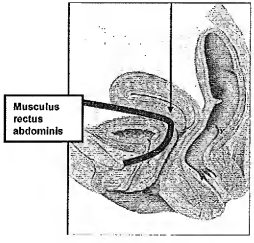


FIGURE 3

In Landgrebe the central portion of the device is called "base 1", and it clearly refers to the triangle-like central portion of the device. The present claims recite the word "bases" meaning the two parallel edges of the trapezoid (i.e. in geometry the smaller or minor base and the larger or major base). Thus, the term "base" in the present claims is totally different from the term "base" used in Landgrebe et al.

In addition to all the structural differences and different objects between the present invention and Landgrebe, it is noted, merely for the sake of argument, that if a surgeon would attempt to use Langrebe's device and attempt to anchor it in the pelvis at the same four anchoring points of the instant device, such could not succeed, as follows.

An attempt to use the Landgrebe device would require several and material modifications, (more than the simple addition of a hole and a cleft), and the result would still not be usable as presently claimed. The modification would have to include

the following steps 1-4 which correspond to reference numbers 1-4 in Figure 4 below, see also page 19 in the Appendix.

1. Arms 3, 4 and legs 7, 8 would have to be shortened and moved wide apart (more than 20° from the longitudinal axis L-L), probably producing folds or overtension at the branching-off points thus weakening their holding capability;
2. A hole has to be made in the triangle-like central portion;
3. The extension 2 in the region between arms 3, 4 has to be cut away, otherwise the bladder neck or the urethra could have been strangulated by this extension; and
4. The base, namely the lower edge of the triangle-like central portion, has to be reversed from convex to concave to avoid strangling the rectum.

These speculative modifications are illustrated in the drawing below with dashed lines to show how the Landgrebe et al. device would have to be reconstructed.

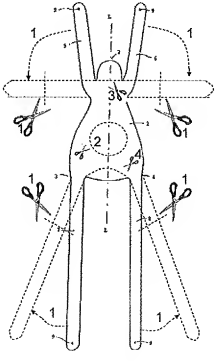


FIGURE 4

It is respectfully submitted that these many modifications cannot be considered obvious under 35 U.S.C. § 103.

COMBINATION OF LANDGREBE WITH REHIL

Rehil was cited for disclosure of a flat inflatable device for correcting organ placement comprising a central portion with a central hole from which starts a cleft. Further study of Rehil shows that it is for hiatal hernia repair to help control gastro-esophageal reflux with the purpose to prevent the stomach from migrating "upward" through the hiatal opening in the diaphragm 24 as seen in Fig. 1 and 2; ring 10 fits snugly around the esophagus 30 to prevent such migration (col. 4, lines 31-34).

Thus, the Rehil device is situated above an organ to prevent upward movement of the organ, and this device has no purpose or ability to support any organ from below or prevent an organ from descending.

It is respectfully submitted that the proposed combination of prior art references is not feasible, because the teachings, objectives, obstacles, environments, limitations and functions of these references are different and remote, and there are no suggestions, motivations or teachings in Landgrebe nor in Rehil to combine them.

In the medical fields different anatomical regions may have greatly different peculiarities due to completely different physiology. Without a clear suggestion to apply disparate disclosures of completely different anatomical regions, combination of such disclosures cannot be inherently obvious. It is respectfully submitted that the Rehil is so remote, unrelated and different, it would not be obvious for combination with Landgrebe et al.

Thus, Rehil discloses a device which is not suitable for supporting the downward load of organs, but at best is used for preventing organs from rising. If a hole of Rehil were added to the Landgrebe device, which is designed for preventing the bladder from falling downward, the result would allow the bladder to fall in the hole, thus defeating

the object of Landgrebe et al., an additional reason why the teaching of Rehil would have not have been obvious for the proposed combination in the rejection.

The above remarks are believed to demonstrate that the device claims 68-78 and the method claims 67 and 79-82 are patentably distinguished over the cited prior art.

In view of the above amendments and remarks, reconsideration and favorable action on all pending claims is respectfully requested.

Respectfully submitted,

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